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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,446	09/08/2000	David E. Edgren	ARC 2762C1	1540

7590

12/28/2004

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,446

Applicant(s)

EDGREN ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46,48,51 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46,48,51 and 53-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR

1.114, request for extension of time and change of address filed 10/12/04. The amendment filed after the final office action is considered; claims 46, 48, 51 and 53-60 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 10/12/04 has been entered.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 46, 48, 51 and 53-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,558,879).

Chen discloses a controlled release dosage form comprising a core of medicament and pharmaceutically acceptable excipients and polymeric binders and osmotic agents. The core is coated with a dual membrane coating where the dual membrane consists of first inner coating layer and a second outer coating layer. See abstract. A 24-hour therapeutic blood level is achievable with this dosage form (column 3, lines 59-64). The inner coating layer consists of plasticized water insoluble pharmaceutically acceptable polymer and a pharmaceutically

Art Unit: 1615

acceptable water-soluble polymer; the second outer coating consists of a medicament and water-soluble polymer (abstract). Water-insoluble polymers applicable in Chen are cellulose esters, cellulose ethers, cellulose acylate, cellulose acetate, cellulose diacetate, ethylcellulose and cellulose ethyl ether. Hydroxymethyl cellulose, hydroxypropyl cellulose or cellulose may be combined with the water insoluble polymer to modify the permeability of the membrane coat around the core (column 5, lines 1-20 and column 6, lines 6-56). The application does not exclude medicine from the outer membrane coat layer. The dosage of Chen would be capable of the release profile recited in claims 55-58 of the application since the dosage form of Chen reads on the claimed dosage form. The teachings of Chen meet the limitations of the claims.

Response to Arguments

Applicants argue that Chen does not teach that the membrane is capable of responding to changes in osmotic pressure. However, response to changes in osmotic pressure is a property of the membrane and it is respectfully noted that no specific membrane material is claimed that would make applicants' membrane semipermeable and the prior art's not. It is also noted that instant claim 1 is directed to hydrophobic or hydrophilic substance that responds to osmotic pressure. Chen is considered as disclosing a hydrophilic substance. The instant claims are broadly directed to osmotic dosage forms.

3. Claims 46, 48, 51 and 53-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartoo et al. (US 4,743,248).

Bartoo teaches an osmotic dosage form comprising an outside wall and an inside wall (abstract). The outside wall comprises semipermeable polymers where the semipermeable polymers are cellulose esters, cellulose ethers, cellulose acylate, cellulose acetate and cellulose

Art Unit: 1615

diacetate and triacetate (column 3, line 54 to column 4 line 5). The inside wall comprises polymeric formulation that is responsive to environmental changes such as pH (column 4, lines 6-9). The internal compartment comprises beneficial agents or active drugs and the dosage form also has an expandable layer (column 4, lines 47-68 and column 7, line 6). In example 1, the cores are coated with an inside wall forming composition comprising hydroxypropylmethylcellulose phthalate, cellulose acetate, sorbitol and polyethylene glycol; and the second outside semipermeable wall is coated onto to the inside wall. The scope of the claims in the application reads broadly on a conventional osmotic dosage form and reads on Bartoo. The dosage of Bartoo would be capable of the release profile recited in claims 55-58 of the application since the dosage form of Bartoo reads on the claimed dosage form. The claimed method is a broad administration of the claimed composition and Bartoo's dosage form is administered to animals. Thus, Bartoo anticipates the claims.

Response to Arguments

Applicants argue that Bartoo does not disclose enteric element that responds to hydrophobicity and time to hydrate. However, the scope of the instant claim 46 is possibility between hydrophobic substance and hydrophilic substance and Bartoo does not have to disclose both. Bartoo only has to disclose one. Bartoo discloses an osmotic dosage form comprising an outside wall and an inside wall. The outside wall comprises semipermeable polymers where the semipermeable polymers are cellulose esters, cellulose ethers, cellulose acylate, cellulose acetate and cellulose diacetate and triacetate. The inside wall comprises polymeric formulation that is responsive to environmental changes such as pH.

Observation/Request:

Art Unit: 1615

It is noted that applicants do not state the section of the specification that supports the amendment and applicants have not disclaimed that no new matter is introduced into the claims by the amendment. Thus there may also be the issue of introduction of new matter into the claims. It is respectfully requested that applicants provide where the specification supports the amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

